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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,330	04/30/2001	George Jackowski	2132.007	3124

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MCHALE & SLAVIN
4440 PGA BLVD
SUITE 402
PALM BEACH GARDENS, FL 33410

EXAMINER
BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Filed Copy

Office Action Summary	Application No. 09/846,330	Applicant(s) JACKOWSKI ET AL.	
	Examiner John S. Brusca	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention: species of interactive mapping steps listed in claims 6 and 9: 1) creation of engineered antibodies, 2) directly determining the three dimensional structure of said antibody directly from an amino acid sequence thereof, 3) cellular localization, 4) sub-cellular localization, 5) protein-protein interaction, 6) receptor-ligand interaction, and 7) pathway delineation. Claims 7 and 10 are drawn to species 1.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-5, and 8 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Ferris Lander on 09 December 2002 a provisional election was made with traverse to prosecute the invention of species 1, claims 1-10. Affirmation of this election must be made by applicant in replying to this Office action. No claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

The drawings filed 30 April 2001 are acceptable.

Specification

It is brought to the applicant's attention that the appendix attached to the application at the time of filing is not part of the specification and will not be published should the instant application issue as a patent. The appendix was not included in the numbered pages of the specification, and was not indicated to be part of the specification in the transmission papers at the time of filing.

The disclosure is objected to because of the following informalities: On page 32, line 15, the specification refers to an Appendix A that is not part of the specification.

Appropriate correction is required.

For the purpose of examination the phrase "interactive mapping step" in claims 5 and 8 are interpreted to read on the elected species of creation of an engineered antibody as defined on page 23 of the specification.

For the purpose of examination the phrases "engineered antibody" of claim 6 and "engineered protein" of claim 9 are both interpreted to read on a labeled antibody as defined in the specification on page 23, lines 14-18.

For the purpose of examination the phrase "expressing at least one protein marker" in claim 4 is interpreted to read on expression of the protein at any point in the method, including prior to isolation of the patient sample.

For the purpose of examination the engineered antibody of claims 6 and 9 are drawn to a method of using an engineered antibody that is used to indirectly detect a protein in the patient sample.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 rejected under 35 U.S.C. 102(e) as being anticipated by Hutchens et al.

The claim is drawn to a method of isolating a protein sample from a patient, comparing the protein sample to a proteomic database, and determining whether the proteomic sample is diagnostic of a disease.

Hutchens et al. shows throughout a method of analysis of proteomic samples by use of retentate chromatography coupled with MALDI-TOF mass spectrometry analysis. Hutchens et al. shows development of a diagnostic assay in columns 4 and 7, and exemplifies a diagnostic

assay in figures 21A-21D (normal versus diseased human serum analysis) and 23A-23D (human cancer patient urine analysis). Hutchens et al. shows comparison to databases and data analysis in columns 34-36, and exemplifies such database comparison in figures 21A-21D and 23A-23D. Hutchens et al. shows the development of diagnostic probes for use with proteomic samples in columns 40-41. Hutchens et al. further shows development of diagnostic proteomic methods in columns 43-44, and as claimed in claim 2, where development of differential expression analysis methods are discussed in the context of diagnostic markers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 3, 4, 5, and 8 and claim 1 from which they depend are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchens et al. in view of Jungblut et al.

The claims are drawn to a method of isolating a protein sample from a patient, comparing the protein sample to a proteomic database, and determining whether the proteomic sample is diagnostic of a disease. In some embodiments the method includes sequencing the proteomic sample, developing an antibody to the proteomic sample, expression of a protein to which the antibody is specific for, and using an antibody to analyze a protein of the sample.

Hutchens et al. shows throughout a method of analysis of proteomic samples by use of retentate chromatography coupled with MALDI-TOF mass spectrometry analysis. Hutchens et al. shows development of a diagnostic assay in columns 4 and 7, and exemplifies a diagnostic assay in figures 21A-21D (normal versus diseased human serum analysis) and 23A-23D (human cancer patient urine analysis). Hutchens et al. shows comparison to databases and data analysis in columns 34-36, and exemplifies such database comparison in figures 21A-21D and 23A-23D. Hutchens et al. shows the development of diagnostic probes for use with proteomic samples in columns 40-41. Hutchens et al. further shows development of diagnostic proteomic methods in columns 43-44, and as claimed in claim 2, where development of differential expression analysis methods are discussed in the context of diagnostic markers. Hutchens et al. does not show methods including sequencing the proteomic sample, developing an antibody to the proteomic

sample, explicit expression of a protein to which the antibody is specific for, or using an antibody to analyze a protein of the sample.

Jungblut et al. shows proteomic analysis methods for disease diagnosis throughout and especially in figure 1. Jungblut et al. shows sequencing of a protein in the sample for the purpose of identification matching in a database on page 2102. Jungblut et al. shows use of antibodies for identification of a hepatocellular carcinoma related protein in figure 4 and page 2103, and for identification of heat shock proteins associated with dilated cardiomyopathy on page 2104. Regarding the limitation of expression of the protein in claim 4, both Hutchens et al. and Jungblut et al. show use of proteins that were expressed in the patient before the sample was obtained.

Claims 6, 7, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchens et al. in view of Jungblut et al. as applied to claims 2, 3, 4, 5, and 8 and claim 1 from which they depend above, and further in view of Watkins.

The claims are drawn to proteomic diagnostic methods that use antibodies labeled with biotin or colloidal gold.

Hutchens et al. in view of Jungblut et al. as applied to claims 2, 3, 4, 5, and 8 and claim 1 from which they depend above does not show antibodies labeled with biotin or colloidal gold.

Watkins shows on pages 14.6.5-14.6.11 that antibodies labeled with biotin or colloidal gold are useful for detecting antigens in histological samples.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Hutchens et al. in view of Jungblut et al. as applied

to claims 2, 3, 4, 5, and 8 and claim 1 from which they depend above by use of the biotin or colloidal gold antibody labeling methods of Watkins because Watkins shows that such labeling methods allow of detection of antigens in histological samples.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746-5137 for regular communications and 703 746-5137 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

John S. Brusca
Primary Examiner
Art Unit 1631

jsb
December 11, 2002